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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/994,068	11/27/2001	Tsutomu Arakawa	06843.0028-02000	8561

22852 7590 10/13/2006

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EXAMINER	
GODDARD, LAURA B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 09/994,068	**Applicant(s)** ARAKAWA ET AL.	
	Examiner Laura B. Goddard, Ph.D.	**Art Unit** 1642	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 21 August 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *19-24,29,30,42 and 43*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☒ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☒ Other: See Continuation Sheet.

Continuation of 13. Other: Claims 19-24, 29, 30, 42, and 43 remain rejected under 112 1st paragraph, because the specification, while being enabling for a method for treating cancer comprising administering mAb74 or fragment thereof to induce apoptosis in Her2 overexpressing cells in cell culture (in vitro), does not reasonably provide enablement for a method for treating cancer in a patient comprising administering an antibody or fragment thereof that binds HER2 and induces apoptosis in Her2 overexpressing cells in vivo. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims (see the Office Action of September 22, 2005, section 5, p. 9-15).

Applicants assert that the specification and the knowledge in the art at the time of filing enable one skilled in the art to make antibodies that bind Her2 and induce apoptosis in Her2 overexpressing cells wihtout undue experimentation. Applicants assert that the specification and the knowledge int eh art at the time of filing enable one skilled in the art to use those antibodies in a method for treating cancer characterized by overexpression of Her2 in a patient. Applicants enclosed copies of review articles that deomnstrate certain methods of administering antibodies to treat conditions in patients were known in the art prior to filing date of the present application.

Examiner maintains the rejection on the basis of lask of enablement for in vivo treatment of cancer overexpressing Her2 comprising adminstering any antibody or fragment thereof that binds Her2 and induces apoptosis in her2 overexpressing cells. Examiner maintains arguments that in vitro studies are not representative or predictive of in vivo treatment and the examples provided by the specification are not enabling. Examiner maintains arguments that cancer treatment is unpredictable and undue experimentation is required to treat Her2 overexpressing cancer in vivo comprising administering an antibody with unexpected properties of inducing apoptosis in Her2 ocerexpressing cells in vitro. Applicants submitted documents and state that they describe successful treatment of a condition by administering an antibody to a patient prior to the filing date of the present application. The documents submitted do not enable treatment of a Her2 overexpressing cancer in vivo comprising adminsitering a Her2 binding antibody that induces apoptosis. Applicants provided an English translation abstract of an article in Japanese, Sasaki et al (Nippon Risho, 2002, 60:451-6), and assert that Sasaki et al supports the conclusion that even though the anti-Her2 antibodies recited in the claims have an unexpected property, that property does not adversly affect the ability of one skilled in the art to use the antibodies in the claimed methods according to the teachings of the specification and knowledge in the art. Examiner suggests filing an RCE to fully consider the newly presented references and arguments for the maintained rejection under 112 1st paragraph.